REMARKS

In response to the Office Action mailed on August 29, 2003, Applicants submit the following Amendment and Response. Claims 55, 57, 62, 64, and 85 have been amended. Claims 68, 73-74, 77-79, 81-82,and 86-89 have been canceled. Claims 53-67, 69-72, 75-76, 80, and 83-85 remain pending. Specification support for these amendments are cited in the discussion of the rejections below. Therefore, these amendments are made without the addition of new matter.

Drawings

The drawings are objected to under 37 CFR 1.83(a) as allegedly failing to show every feature of the invention specified in the claims. In particular, the examiner alleges that the drawings fail to illustrate the method steps for identifying tissue that is located within a predetermined distance of a boundary of a biopsy cavity, as claimed in claims 53-89. Without conceding the propriety of the rejection, applicants have submitted additional Figs. 8-12 and a brief description of each figure. These figures correspond to Figs. 3-8 of U.S. Provisional Application 60/090,243, filed June 22, 1998. The '243 application was incorporated by reference in the present specification. (See page 10, lines 3-4). Therefore, these figures were added without the addition of new matter. In addition, Applicants respectfully assert that the currently pending figures do illustrate every feature of the invention specified in the claims. Applicants point to Figs. 3-5, which applicants believe illustrates method steps for introducing a detectable marker into a site from which a tissue sample has been removed as described in the pending claims.

35 U.S.C. § 112

Claims 53-89 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide enablement for dictating the amount of time the bioabsorbable element remains at the site. (Office Action, page 3) Specifically, the examiner alleges that the specification does not disclose: staying at the site for a predetermined amount of time to permit the relocation of the biopsy site; the marker interferes with the imaging of the surrounding tissue during a first time but not after a second time point, and a time frame of "2 weeks" as stated in claim 62. Applicants respectfully assert that these elements are disclosed in the specification and the provisional applications, which are incorporated by reference and to which the current applications claim priority. For example, in Application Serial No. 60/090,243 (hereinafter "the '243 application"), the specification describes how the device "will serve as a temporary marker for subsequent surgery .... The device would allow the surgeon to visually and tactilely locate the previously biopsied site. It is also an object of the present invention that the device be biodegradable and resorbable, allowing the device to gradually vanish in women with benign diagnoses, obviating the unneeded permanent metallic marker in the great majority of women undergoing breast biopsies." (the '243 application, page 6, lines 8-17). This provisional application also describes a marker that "must not be significantly resorbed for at least **two weeks** after it is deployed or implanted within the breast." (emphasis added) (the '243 application, page 9, lines 1-3). In addition, the specification of the current application states that "the bioabsorbable material will typically be absorbed within about a month of placement." (page 3, lines 14-15).

The examiner also alleges that the specification fails to disclose the use of CT, MRI, Doppler, and radiation detection means for locating the marker. (Office Action, page 4). In

Provisional Application Serial No. 60/117,421, the specification states that, "it may be desirable ... to locate the device by means other than palpation, i.e., either ultrasound, **MRI**, mammography, etc." (emphasis added) (Provisional Application Serial No. 60/117,421, page 9, lines 9-11). Applicants believe that "computer tomography," "Doppler," and "radiation detection" are obvious variations of the detection means disclosed in the specification and provisional applications. Without conceding the propriety of the rejection, claim 55 has been amended to delete "computer tomography," "Doppler," and "radiation detection."

The examiner also alleges that the specification fails to disclose a palpable marker consisting of at least one bead and a cross-linked gelatin. (Office Action, page 4) Applicants believe that "bead" and "pellet" are obvious variations of each other. The Merriam-Webster Dictionary defines "bead" as "a small ball-shaped body" and "pellet" as "a usually small rounded, spherical, or cylindrical body (as of food or medicine)." (See www.m-w.com) Nonetheless, claim 57 has been amended to delete "cross-linked gelatin" and claim "at least one pellet." Support for this amendment can be found in the specification at, e.g., page 3, lines 6-10.

The examiner alleges that the specification fails to disclose the use of a visualization means for the marker element, including a coloring means using dyes and carbon. Applicants respectfully assert that the visualization means is described in the specification at, e.g., page 4, lines 28-29, where the "use of a coloring agent, such as methylene blue or some other dye" is mentioned. Additionally, the '243 application states that "[i]t may be advantageous to enhance the visual detectability of the device by coloring it or causing it to contain a bioresorbable color such as methylene blue or other dye." ('243 application, page 8, lines 9-12). With regard to "carbon," applicants respectfully point

the examiner to page 2, lines 16-18 or the specification, where a procedure is described that "injects medical-grade powdered carbon suspension from the lesion to the skin surface."

The examiner alleges that the specification fails to disclose the use of a clearance delaying element using an encapsulating material, renatured collagen, renatured gelatin, and/or cross-linked gelatin. (Office Action, page 4) Although applicants believe that "renatured" and "cross-linked" materials are obvious variations of the materials disclosed in the present specification and provisional applications, claim 64 has been amended to delete "renatured collagen," "renatured gelatin," and "cross-linked gelatin." With regard to the "encapsulating material," support can be found in the '243 application, which states "[b]ecause some materials may react with blood or other fluids before being completely deployed, a thin coating of a second material may be needed to permit the device to be completely deployed. It is anticipated that the second material would be rather quickly biodegradable, which would allow the first material to expand or react with body fluids soon after deployment." ('243 application, page 8 lines 3-8). Similarly, in Provisional Application Serial No. 60/114,863 (the '863 application), an encapsulating material is described on page 12, lines 7-9 ("One solution is to cover all or a portion of the marker device with a thin layer or film of bioresorbable material which does not immediately react with or absorb blood or body fluids.")

The examiner also alleges that the specification fails to disclose a marker comprising a dry powder, a sponge, a liquid, collagenous material with radiographically imageable material attached to the marker, and the material comprising ions. With respect to the rejection to "dry powder," although applicants believe that this is an obvious variation of the materials disclosed in the present specification and provisional applications, claim 68 has been canceled. With respect to the rejection

to "sponge," applicants respectfully submit that the Merriam-Webster Dictionary defines "sponge" as "a porous rubber or cellulose product used similarly to a sponge." (See www.m-w.com) Therefore, support for a detectable marker comprising a sponge (see claim 69) can be found in the specification at, e.g., page 10, lines 18-22 of the '243 application. With respect to a marker comprising a "liquid," support for this embodiment can be found in the '243 application at page 9, lines 15-17. With respect to a marker comprising "collagenous material," support for this embodiment can be found in the '243 application at page 10, lines 18-22. With respect to a marker comprising ions, support for this embodiment can be found in the '243 application at page 7, line 22 – page 8, line 2. Applicants have also amended claim 85 to delete the term "renatured" so that it now claims a marker comprising "ions that are bound to said gelatin." Applicants believe that renatured and cross-linked collagen are obvious variations of the collagenous material described in the instant specification and provisional applications. Nevertheless, without conceding the propriety of this rejection, claims 72, 73, 77 and 82 have been canceled. Therefore, these rejections are now moot.

With respect to the rejections to the method steps in claims 78 and 79 concerning denatured and renatured collagen, without conceding the propriety of this rejection, claims 78 and 79 have been canceled. Therefore, this rejection is now moot.

With respect to the rejections to the method steps in claims 86 and 87 concerning denatured and renatured gelatin, without conceding the propriety of this rejection, claims 86 and 87 have been canceled. Therefore, this rejection is now moot.

With respect to the rejections to the method steps in claims 88 and 89, without conceding the propriety of this rejection, claims 88 and 89 have been canceled. Therefore, this rejection is now moot.

Claim 62 was rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention. In particular, the examiner alleges that there is insufficient antecedent basis for "said first time point." Applicants have amended claim 62 to clarify that "*a clearance delaying element that delays the clearance of said material from the site such that (i) a detectable quantity of said material remains present at the site until at least 2 weeks after introduction of said detectable marker and ....*"

Therefore, applicants respectfully request withdrawal of the rejections and reconsideration of the claims as amended.

35 U.S.C. § 103

Claims 53-61, 65-71, 88, and 89 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al. (USP 6,228,055). Claims 62-64 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al., and further in view of Unger et al. (USP 6,231,834). Claims 72-76 and 80-87 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al., and further in view of Ragheb et al. (USP 5,873,904). Claims 77-79 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al., and further in view of Vogel et al. (USP 6,335,028).

Applicants respectfully argue that the Foerster reference does not disclose a bioabsorbable element that remains at the site for a predetermined first time period. Claim 1 requires a marker to remain "*present at the site in sufficient quantity to permit detection and location of the site for at least a predetermined first time period.*" Foerster et al. only discloses that a biodegradable polymer may be used. (See Col. 13, lines 33-36) It does not disclose a predetermined time period that the bioabsorbable element must remain at the site. Therefore, applicants respectfully request withdrawal of the rejections and reconsideration of the claims as amended.

In addition, applicants wish to point out that U.S. Patent No. 6,161,034 (the Burbank '034 patent), from which the present claims were copied, was allowed over this reference. More specifically, the corresponding international application WO 96/08208 A1 was cited and of record in the '034 patent. Therefore, the present claims are allowable for the same reasons that the Burbank claims were allowed to issue.

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Applicants submit that the claims, as amended, are free of the cited art and are in position for allowance. Please charge Deposit Account No. **50-2862** for the 3-month extension fee and any other fees required by this submission. If the Examiner has any questions regarding this communication, or feels that an interview might facilitate prosecution of the application, he is invited to contact the undersigned at (949) 737-2900.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: February 27, 2004

By: Diane K. Wong
Diane K. Wong
Reg. No. 54,550

JCK/DKW

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PATENT TRADEMARK OFFICE
O'Melveny & Myers LLP
114 Pacifica, Suite 100
Irvine, CA 92618-3315
(949) 737-2900

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